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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,315	04/12/2004	Bryan Leasure	1001.1749101	2606
28075	7590	07/05/2006	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420			HELLER, TAMMIE K	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/822,315	LEASURE, BRYAN	
	<b>Examiner</b>	<b>Art Unit</b>	
	Tammie Heller	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 8-10 and 18-26 is/are rejected.
- 7) ☒ Claim(s) 4, 6, 7 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

1. The amendment filed on February 13, 2006 has been received and considered. By this amendment, claims 1 and 3 have been amended and claims 1-10 and 17-26 are now pending in the application.

#### ***Response to Arguments***

2. Applicant's arguments with respect to claims 1-10 and 17 have been considered but are moot in view of the new ground(s) of rejection.

3. Applicant's arguments filed February 13, 2006 regarding the rejection of claims 18-20, 24, and 25 under 35 U.S.C. 102(b) as being anticipated by Schiff have been fully considered but they are not persuasive. In response to Applicant's argument that Schiff does not disclose an intravascular pump, specifically the structure of Schiff cannot be described as a wall making up a pumping chamber with a frame attached to the wall, it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Therefore, because Schiff discloses the structural elements of claim 18, an umbrella portion 26, constructed of a flexible material such as polyurethane (see col. 2, ln. 34-35), which acts as the flexible wall, and a frame 28 attached to the wall.

4. Applicant's arguments filed February 13, 2006 regarding the rejection of claims 19-26 have been fully considered but they are not persuasive. The Applicant argues that because claims 19-26 depend from claim 18, they are similarly allowable.

However, as shown above, claim 18 is not allowable over the prior art, and therefore claims 19-26 are rejected as well.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 3 recites the limitation "the shape memory material" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-3, 5, 8-10, 18, 19, 21, 23, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Moulder (U.S. Patent No. 5,725,004). Regarding claim 1, Moulder discloses a canopy and canopy operator which includes a flexible canopy 12, a frame 15 attached to the canopy, an elongate member 14 attached to the frame 15 and extending through the cavity, and an actuation system 18 comprising one or more actuating members which connect the frame 15 to the elongate member 14 and configured to move the frame between an expanded position and a contracted position

Art Unit: 3766

(see Figures 1 and 2). The canopy 12 is disclosed to be used in an umbrella assembly requiring a waterproof canopy (see col. 1, ln. 9-11), and therefore is considered to be a blood-impermeable wall.

10. Regarding claims 2, 3, and 5, Moulder discloses that the actuation system 18 may be made of a "smart material", including "shape memory" materials and electroactive polymers (see col. 8, ln. 49-67 and col. 9, ln. 1-14). Moulder discloses that it may be necessary to apply an electric field to the shape memory material, and therefore it is inherent that the struts formed by the shape memory material are electrically connected to a voltage source (see col. 8, ln. 55).

11. Regarding claim 8, it can be seen from Figure 2 that the cross-section of the cavity formed by canopy 12 at the first end is larger than a cross-section of the cavity at the second end when the frame is in the expanded position.

12. Regarding claims 9 and 10, the shape of the cavity formed by canopy 12 can be adjusted based on the force with which actuation system 18 pushes against the canopy 12. Therefore, the cavity may have a generally conical shape when the actuation system 18 pushes slightly against the canopy 12, or a slightly flattened conical shape when the actuation system 18 completely opens canopy 12.

13. Regarding claim 18, Moulder discloses an umbrella including a flexible wall 12 and a frame 15 attached to the wall (see Figure 2). It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

14. Regarding claim 19, Moulder discloses a central shaft 14 and movable struts 18 which extend between the central shaft and the frame (see Figure 1-3).

15. Regarding claims 21 and 23, Moulder discloses that the struts 18 may be made of a "smart material", including "shape memory" materials and electroactive polymers (see col. 8, ln. 49-67 and col. 9, ln. 1-14).

16. Regarding claim 24, Moulder discloses that a control system is employed at or on the elongate member 14 to control the movement of struts 18.

17. Claims 18-20, 24, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Schiff, previously cited. Regarding claim 18, Schiff discloses an umbrella portion 26, constructed of a flexible material such as polyurethane (see col. 2, ln. 34-35), which acts as the flexible wall, and a frame 28 attached to the wall (see Figure 3).

18. Regarding claim 19, Schiff discloses a central shaft 22 and struts 29 extending between the central shaft 22 and the frame 28 (see Figure 3).

19. Regarding claim 20, Schiff discloses that the apparatus 20 includes balloon portion 24 (see Figure 3).

20. Regarding claim 24, Schiff discloses a control system 100 for controlling the pumping action of apparatus 20 (see Figure 12).

21. Regarding claim 25, Schiff discloses that the control system 100 is operated based on an electrocardiogram signal coupled to the controller by a three-wire circuit (see Abstract, lines 36-38).

***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff in view of Breznock, previously cited. Schiff discloses the invention essentially as claimed, including a memory material (see col. 7, ln. 25-29) but does not mention a means to move the shape memory alloy through its transformation temperature. Breznock discloses a medical device which utilizes shape memory material, specification Nitinol (see col. 3, ln. 42) and uses an electrical current to move the shape memory alloy through its transformation temperature, allowing the material to be used as an actuation device. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize a shape memory material, such as Nitinol, in conjunction with an electrical current to move the material through its transformation temperature, as taught by Breznock, in the invention of Schiff, in order to utilize the memory material as an actuation device.

24. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff. Schiff discloses the invention essentially as claimed, including a memory material (see col. 7, ln. 25-29) but does not disclose the use of an electroactive polymer. It would have been obvious at the time of the invention to utilize an electroactive polymer in the invention of Schiff, since it has been held to be within the general skill of a worker in the

Art Unit: 3766

art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

25. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schiff in view of Choy, previously cited. Schiff discloses the invention essentially as claimed, but fails to disclose the use of a pacemaker to control the apparatus. Choy discloses a medical device, specifically a heart assist device, which teaches the use of a pacemaker to control the device (see Figure 25) in order to effectively actuate the heart assist device (see col. 13, ln. 67 and col. 14, ln. 1-3). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize a pacemaker, as taught by Choy, in conjunction with the device of Schiff in order to effectively actuate the heart assist device.

#### ***Allowable Subject Matter***

26. Claims 4, 6, 7, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

27. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Yamamoto (U.S. Patent No. 6,079,430) which discloses an umbrella including a canopy, a frame, an elongate member, and an actuation system;



Daniel et al. (U.S. Patent No. 6,053,932) which discloses an emboli capturing system;

Murphy et al. (US 2004/0249408), which discloses a device for endoscopic surgical ventricular repair.

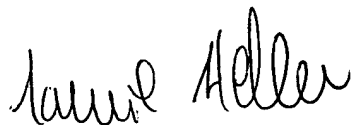
28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tammie Heller whose telephone number is 571-272-1986. The examiner can normally be reached on Monday through Friday from 7am until 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Tammie K. Heller  
Patent Examiner  
Art Unit 3766



Robert E. Pezzuto  
Supervisory Patent Examiner  
Art Unit 3766

TKH